**UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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| ROCHESTER DRUG CO-OPERATIVE, INC., on behalf of itself and all others similarly situated,<br><br>Plaintiff,<br><br>v.<br><br>ACTAVIS ELIZABETH, LLC; TEVA PHARMACEUTICALS USA, INC., PLIVA, INC., IMPAX LABORATORIES, INC., MYLAN INC., MYLAN PHARMACEUTICALS INC., UDL LABORATORIES, INC., ENDO INTERNATIONAL PLC, PAR PHARMACEUTICAL HOLDINGS, INC., HERITAGE PHARMACEUTICALS INC., BRECKENRIDGE PHARMACEUTICALS, INC., and UPSHER-SMITH LABORATORIES, INC.,<br><br>Defendants. | Civil Action No.<br><br>JURY TRIAL DEMANDED |

**DIRECT PURCHASER CLASS ACTION COMPLAINT**

Plaintiff Rochester Drug Co-Operative, Inc. ("RDC" or "Plaintiff") brings this class action, on behalf of itself and all others similarly situated against Defendants Actavis Elizabeth, LLC ("Actavis"), Teva Pharmaceuticals USA, Inc., Pliva, Inc. (together with the Teva defendant, "Teva"), Impax Laboratories, Inc. ("Impax"), Mylan Inc., Mylan Pharmaceuticals, Inc., UDL Laboratories, Inc. (together with the Mylan defendants, "Mylan"), Endo International plc, Par Pharmaceutical Holdings, Inc. (together with the Endo defendant, "Endo"), Heritage Pharmaceuticals Inc. ("Heritage"), Breckenridge Pharmaceuticals, Inc. ("Breckenridge"), and Upsher-Smith Laboratories, Inc. ("Upsher-Smith"), based upon personal knowledge as to facts pertaining to itself, and upon information and belief as to all other matters, and alleges as follows:

## I. INTRODUCTION

1. This is a civil antitrust action seeking treble damages arising out of the Defendants' unlawful scheme to fix, maintain, and stabilize the prices of generic Propranolol tablets and capsules (together, "Propranolol").

2. Generic drugs – drugs that are equivalent to brand name drugs – have saved direct purchasers, consumers, and the American healthcare system tens of billions of dollars annually because they typically introduce competition into a market where none previously existed. Typically, when a first generic drug manufacturer enters a branded market, the generic drug is priced slightly lower than the branded drug. However, the appearance of a second generic drug manufacturer reduces the average generic price to nearly half the brand name price.

As additional generic manufacturers enter the market, prices usually continue to fall. For branded products that attract a large number of generic manufacturers, the average generic price can fall to a small fraction of the branded price.

3. Over the last several years, however, that price dynamic has changed for a large number of generic drugs. Prices for dozens of generic drugs have skyrocketed for no apparent reason. These unusual price increases have sparked investigations by Congress, the United States Department of Justice Antitrust Division ("DOJ"), state attorney generals, and the media. These investigations have begun to reveal a reportedly broad, well-coordinated, and long-running series of schemes to fix prices, allocate markets, and rig bids for a number of generic drugs in the United States. These investigations have also revealed that Defendants' collusion on generic drug prices was centered around trade associations, such as the Generic Pharmaceutical Association ("GPhA"), customer conferences, and other industry gatherings. As part of these ongoing investigations, the DOJ convened a grand jury in this District. This grand jury has issued subpoenas and other requests for information to various generic drug manufacturers on a variety of generic drugs.

4. Recently, on December 12, 2016, the DOJ filed the first two criminal charges stemming from this investigation. *See United States of America v. Jeffrey A. Glazer*, No. 2:16-cr-00506-RBS (E.D. Pa.); *United States of America v. Jason T. Malek,* No. 2:16-cr-00508-RBS (E.D. Pa.). These cases are both pending in this District and allege that these former senior executives of generic drug maker Heritage (a Defendant here) violated Section 1 of the Sherman

Act by participating in conspiracies to fix prices, rig bids and allocate customers for generic Glyburide and Doxycycline. Evidence reportedly unearthed in a related case indicates that Mr. Glazer and Mr. Malek of Defendant Heritage specifically discussed selling Propranolol at a "high price" in early 2015. Evidence also reportedly shows that Mr. Malek compiled a large list of generic drugs and instructed employees to contact competitors, such as Teva and Mylan, to reach agreement to increase prices and allocate customers.

5. According to a June 26, 2016 report by Policy and Regulatory Report ("PaRR Report), the DOJ's investigation is focusing on trade associations and is wide-ranging:

> A PaRR source says prosecutors see the case much like its antitrust probe of the auto parts industry, which has gone on for years and morphed into the department's largest criminal antitrust probe ever. Like in that case, prosecutors expect to "move from one drug to another in a similar cascading fashion.[1]

6. Propranolol is on the World Health Organization's List of Essential Medicines. Propranolol is a medication of the beta blocker type. Beta blockers work by blocking the effects of the hormone epinephrine. When a patient takes beta blockers, her heart beats more slowly and with less force, thereby reducing blood pressure. Beta blockers can also help blood vessels open up to improve blood flow.

7. Propranolol was discovered in the 1960s. Generic versions of Propranolol have been on the United States market for decades. For much of that time, generic versions of

[1] Eric Palmer, *DOJ Criminal probe takes a look at trade associations*, FiercePharma (July 10, 2015), *available at* http://www.fiercepharma.com/regulatory/doj-criminal-probe-takes-a-look-at-trade-associations.

Propranolol have been priced significantly lower than their branded counterparts. This is because the presence of multiple competing versions of generic drugs usually results in vigorous price competition, benefiting direct purchasers and consumers through lower prices.

8. However, recently, the price of generic Propranolol has experienced unusual and unprecedented prices increases.

**A. Propranolol Capsules**

9. Beginning in December 2013, Defendants caused the price of Propranolol extended release ("ER") capsules ("Propranolol Capsules") to dramatically increase in unison. The increases were the result of an agreement among Defendants to increase pricing and restrain competition for the sale of Propranolol Capsules in the United States. The agreement was furthered by discussions held at GPhA meetings, including a meeting in Bethesda, Maryland in October 2013 that was attended by Defendants, as well as other meetings and communications.

10. Defendants Mylan, Actavis, Breckenridge, and Upsher-Smith sold Propranolol Capsules during the Class Period (as defined below). Within a few weeks of the October 2013 meeting, average prices for Propranolol Capsules increased an average of 173% across dosage strengths. These prices increases were, for the most part, in lockstep.

**B. Propranolol Tablets**

11. Beginning in February 2015, Defendants caused the prices of the tablet formulation of Propranolol ("Propranolol Tablets") to dramatically increase in unison. The increases were the result of an agreement among Defendants to increase pricing and restrain

competition for the sale of Propranolol Tablets in the United States. The agreement was furthered by discussions held at GPhA meetings, including a meeting in Miami Beach, Florida in February 2015 that was attended by Defendants, as well as other meetings and communications.

12. Defendants Mylan, Actavis, Teva, Endo, and Heritage sold Propranolol Tablets during the Class Period (as defined below). Prior to February 2015, the average amount paid for Propranolol Tablets in the United States was stable. However, within a few weeks of the February 2015 meeting, average prices for Propranolol Tablets increased an average of 736% across dosage strengths. These price increases were, for the most part, in lockstep.

**C. These Price Hikes are the Result of Defendants' Collusion**

13. The price hikes have not been the result of competitive market forces. Instead the price hikes were the result of Defendants' conspiracy to fix, raise, maintain and stabilize the prices of, and/or allocate customers and markets and rig bids for, Propranolol. The price increases were neither the product of a competitive market, nor made necessary by any increased manufacturing costs. And because generic pharmaceutical manufacturers do not need to incur the research and development costs that brand manufacturers invest to develop new prescription drugs, Defendants' price increases cannot be attributed to the need to fund research and development. Defendants' price increases resulted from their conspiracy to restrain trade.

14. *Inter alia*, Defendants realized their conspiracy through private and public communications and meetings such as trade association meetings held by the GPhA. Given the small number of competitors and the high barriers to entry in the market for Propranolol the

market was ripe for collusion. Defendants recognized this and engaged in anticompetitive actions that allowed them to sustain their unlawful supracompetitive pricing.

15. At least five Defendants —Actavis, Teva, Mylan, Impax, and Par—have been subpoenaed by the DOJ's grand jury in this District as part of its ongoing investigation of anticompetitive practices in the generic pharmaceutical industry. In a November 9, 2016 10-Q, Mylan stated that the subpoena it received sought information from the company, "as well as certain employees and a member of senior management . . . relating to the marketing, pricing and sales . . . and any communications with competitors" concerning Propranolol as well as several other generic drug products.

16. Defendants have collectively and unlawfully colluded to restrain and/or eliminate competition by engaging in an anticompetitive conspiracy designed to raise prices and foreclose competition in at least the markets for Propranolol in the United States, in violation of Section 1 of the Sherman Act. This misconduct enabled each and every Defendant to overcharge direct purchasers for Propranolol

17. As a result of Defendants' scheme to fix, raise, maintain, and stabilize the prices of Propranolol, direct purchasers such as Plaintiff RDC, have paid and continue to pay supracompetitive prices.

18. RDC brings this civil antitrust action on behalf of proposed class of purchasers who directly purchased Propranolol Capsules and/or Propranolol Tablets.

## II. JURISDICTION AND VENUE

19. This action arises under section 1 of the Sherman Act, 15 U.S.C. § 1 and section 4 of the Clayton Act, 15 U.S.C. § 15(a), and seeks to recover treble damages, costs of suit and reasonable attorneys' fees for the injuries sustained by RDC and members of the proposed Class (defined below) resulting from Defendants' conspiracy to restrain trade in the United States. The Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a), 1407, and 15 U.S.C. § 15.

20. Venue is proper in this District pursuant to 15 U.S.C. §§ 15(a), 22 and 28 U.S.C. §§ 1391(b), (c), and (d) because during the Class Period (defined below), the Defendants resided, transacted business, were found, or had agents in this District, and a substantial portion of the alleged activity affected interstate trade and commerce discussed below has been carried out in this District.

21. During the Class Period, Defendants sold and shipped generic drugs in a continuous and uninterrupted flow of interstate commerce, which included sales of Propranolol in the United States, including in this District. Defendants' conduct had direct, substantial, and reasonably foreseeable effects on interstate commerce in the United States, including in this District.

22. This Court has personal jurisdiction over each Defendant because, *inter alia*, each Defendant: (a) transacted business throughout the United States, including in this District; (b) participated in the selling and distribution of Propranolol throughout the United States,

including in this District; (c) had and maintained substantial contacts with the United States, including in this District; or (d) was engaged in an unlawful conspiracy to inflate the prices for Propranolol that was directed at and had the intended effect of causing injury to persons residing in, located in, or doing business throughout the United States, including in this District.

## III. PARTIES

### A. Plaintiff

23. Plaintiff Rochester Drug Co-Operative, Inc. is a stock corporation duly formed and existing under the New York Cooperative Corporations Law, with its principal place of business at 50 Jet View Drive, Rochester, New York 14624. During the Class Period, as defined below, RDC purchased Propranolol directly from one or more of the Defendants at supracompetitive prices thereby suffering injury to its business and property.

### B. Defendants

24. Defendant Actavis Elizabeth, LLC ("Actavis") is a Delaware limited liability company with its principal place of business in Elizabeth, New Jersey. In March 2015, Actavis, plc completed a merger with Allergan, plc ("Allergan") and adopted Allergan's name. In August 2016, Teva (defined below) purchased the Actavis generics business, which included Defendant Actavis, from Allergan. During the Class Period, Actavis sold Propranolol Capsules and Tablets in this District and throughout the United States.

25. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA's

parent corporation is Teva Pharmaceutical Industries, Ltd., an Israeli corporation with its principal place of business in Petach Tikva, Israel. During the Class Period, Teva USA sold Propranolol Capsules and Tablets in this District and throughout the United States.

26. Defendant Pliva, Inc. ("Pliva") is a New Jersey corporation with its principal place of business in East Hanover, New Jersey. Pliva is a subsidiary of Teva USA's parent corporation, Teva Pharmaceutical Industries, Ltd. During the Class Period, Pliva sold Propranolol Tablets in this District and throughout the United States.

27. Defendants Teva USA and Pliva are together referred to as "Teva."

28. Defendant Impax Laboratories, Inc. ("Impax") is a Delaware corporation with its principal place of business in Hayward, California. During the Class Period, Impax sold Propranolol Tablets in this District and throughout the United States. Impax acquired the rights to sell Propranolol Tablets from Teva in 2016 and Impax's President and CEO noted during a 2016 earnings call that the company was "especially pleased" to be adding Propranolol to its offerings due to the drug's "attractive margin profile."

29. Defendant Mylan Inc. is a Pennsylvania corporation with its principal place of business in Canonsburg, Pennsylvania. The parent corporation of Mylan Inc. is Mylan N.V., a Netherlands corporation with global headquarters in Hertfordshire, United Kingdom, and in Canonsburg, Pennsylvania. During the Class Period, Mylan Inc. sold Propranolol Capsules and Tablets in this District and throughout the United States through its subsidiaries, Mylan Pharmaceuticals Inc. and UDL Laboratories, Inc.

30. Defendant Mylan Pharmaceuticals Inc. is a West Virginia corporation with its principal place of business in Morgantown, West Virginia. During the Class Period, Mylan Pharmaceuticals Inc. sold Propranolol Capsules and Tablets in this District and throughout the United States.

31. Defendant UDL Laboratories, Inc. ("UDL") is an Illinois corporation with its principal place of business in Rockford, Illinois. UDL is, and was throughout the Class Period, a subsidiary of Mylan, Inc. During the Class Period, UDL sold Propranolol Tablets in this District and throughout the United States.

32. Defendants Mylan Inc., Mylan Pharmaceuticals Inc., and UDL are together referred to as "Mylan."

33. Defendant Endo International PLC ("Endo International") is an Irish corporation with its principal place of business located in Dublin, Ireland and United States headquarters in Malvern, Pennsylvania. During the Class Period, Endo International's subsidiary Qualitest Pharmaceuticals, Inc. sold Propranolol Tablets in this District and throughout the United States.

34. Defendant Par Pharmaceutical Holdings, Inc. ("Par"), is a Delaware corporation with its principal place of business in Chestnut Ridge, New York. In September 2016, Endo International completed an acquisition of Par at which time it created a combined United States Generics segment that included Par and Qualitest, naming the segment Par Pharmaceutical, an Endo International Company. On information and belief, Qualitest merged into Par.

35. Defendants Endo International and Par are together referred to as "Endo."

36. Defendant Heritage Pharmaceuticals Inc. ("Heritage") is a Delaware corporation with its principal place of business in Eatontown, New Jersey. During the Class Period, Heritage sold Propranolol Tablets in this District and throughout the United States. Heritage is a subsidiary of Emcure Pharmaceuticals Ltd., based in Pune, India.

37. Defendant Breckenridge Pharmaceuticals, Inc. ("Breckenridge") is a Delaware corporation with its principal place of business in Fairfield, New Jersey. During the Class Period, Breckenridge sold Propranolol Capsules in this District and throughout the United States.

38. Defendant Upsher-Smith Laboratories, Inc. ("Upsher-Smith") is a Minnesota corporation with its principal place of business in Maple Grove, Minnesota. During the Class Period, Upsher-Smith sold Propranolol Capsules in this District and throughout the United States.

39. All of Defendants' actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' various officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs (or that of their predecessors-in-interest) within the course and scope of their duties and employment, or with the actual, apparent, or ostensible authority of Defendants.

## IV. UNIDENTIFIED CO-CONSPIRATORS

40. Other persons, firms, entities and corporations, not named as Defendants in this Complaint, have participated as co-conspirators with Defendants in the violations alleged herein,

and have aided, abetted, and performed acts and made statements in furtherance of the conspiracy.

41. The true names and capacities of these unidentified co-conspirators, whether individual, corporate, associate, or representative, are unknown to Plaintiff at this time. Plaintiff may amend this Complaint, as necessary, to allege the true names and capacities of additional co-conspirators as their identities become known through discovery.

42. At all relevant times, other persons, firms, and corporations, referred to herein as "co-conspirators," the identities of which are presently unknown, have willingly conspired with Defendants in their unlawful scheme as described herein.

43. The acts alleged herein that were done by each of the co-conspirators were fully authorized by each of those co-conspirators, or were ordered or committed by duly authorized officers, managers, agents, employees, or representatives of each co-conspirator while actively engaged in the management, direction, or control of its affairs.

## V. FACTUAL ALLEGATIONS

### A. Generic Drug Market Overview

44. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), manufacturers that create a new drug must obtain FDA approval to sell the product by filing a New Drug Application ("NDA"). 21 U.S.C. §§ 301-392. An NDA must include specific data concerning the safety and effectiveness of the drug, as well as information on applicable patents. 21 U.S.C. § 355(a), (b).

45. The Hatch-Waxman Act, enacted in 1984, simplified the regulatory hurdles for

prospective generic manufacturers by eliminating the need for them to file lengthy and costly NDAs.[2] The Hatch-Waxman Act allows a manufacturer seeking approval to sell a generic version of a brand drug to file an Abbreviated New Drug Application ("ANDA"). An ANDA relies on the scientific findings of safety and effectiveness included in the brand manufacturer's NDA, and must show that the generic drug contains the same active ingredient(s), dosage form, route of administration, and strength as the brand drug, and is absorbed at the same rate and to the same extent as the brand drug. This establishes that the generic drug is pharmaceutically equivalent and bioequivalent (together, "therapeutically equivalent") to the brand drug. The FDA assigns generic drugs that are therapeutically equivalent to and are of the same dosage strength and form as their brand counterpart an "AB" rating.

46. The purpose of this coding is to allow users to determine whether the FDA has evaluated a particular approved product as therapeutically equivalent to other pharmaceutically equivalent products and to provide information on the basis of the FDA's evaluations. Thus, generic drugs that are AB rated to the brand share the same safety and efficacy characteristics and are the same dosage size and form.

47. Generic drugs typically provide consumers with a lower cost alternative to brand drugs while providing the same treatment. Specifically:

> A generic drug is the same as a brand-name drug in dosage, safety, strength, quality, the way it works, the way it is taken and the way it should be used. FDA requires generic drugs have the same high quality, strength, purity and stability as brand-

[2] *See* Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984).

name drugs.[3]

48. Drug products are considered to be therapeutic equivalents only if they are pharmaceutical equivalents and if they can be expected to have the same clinical effect and safety profile when administered to patients under the conditions specified in the labeling.[4]

49. Generic versions of brand drugs are priced significantly below the brand versions. Generic versions are liberally and substantially substituted for their brand counterparts. In every state, pharmacists are permitted (and, in some states, required) to substitute a generic product for a brand product unless the doctor has indicated that the prescription for the brand product must be dispensed as written. States adopted substitution laws following the enactment of the Hatch-Waxman Act.

50. The FDA has recognized that typically "[g]eneric competition is associated with lower drug prices[.]"[5] A Federal Trade Commission study reached the same conclusion finding that typically in a "mature generic market, generic prices are, on average, 85% lower than the pre-entry branded drug prices."[6] Economic literature in the healthcare market further confirms

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[3] Food and Drug Administration, Generic Drugs: Questions and Answers, *available at* http://www.fda.gov/Drugs/ResourcesForYou/Consumers/QuestionsAnswers/ucm100100.htm.

[4] Food and Drug Administration, Orange Book Preface, 36th Edition, *available at* http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm.

[5] Food and Drug Administration, Generic Competition and Drug Prices, *available at* http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm.

[6] Federal Trade Commission, Pay-For-Delay: How Drug Company Pay-Offs Cost Consumers Billions, at 8 (Jan. 2010), *available at* https://www.ftc.gov/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff.

that competition by generic products results in lower prices for consumers. In the period before generic entry, a brand drug commands 100% of the market share for that drug and the brand manufacturer can set the price without the impact of normal competitive market forces. Once the first generic enters the market, however, a brand drug rapidly loses sales, on average losing 90% of its sales within a year.[7]

51. A mature generic market, such as the market for Propranolol, has several generic competitors. Because each generic is readily substitutable for another generic of the same brand drug, the products typically behave like commodities, with pricing being the main differentiating feature and the basis for competition among manufacturers.[8] Over time, generics' pricing nears the generic manufacturers' marginal costs.

52. Generic competition usually enables purchasers to (a) purchase generic versions of the brand drug at a substantially lower price than the brand drug, and/or (b) purchase the brand drug at a reduced price. Generic competition to a single blockbuster brand drug product can result in billions of dollars in savings to direct purchasers, consumers, insurers, local, state, and federal governments, and others. Indeed, one study found that the use of generic medicines saved the United States healthcare system $254 billion in 2014 alone, and $1.68 trillion between

[7] *Id*.

[8] *See*, *e.g.*, Federal Trade Commission, Authorized Generic Drugs: Short-Term Effects And Long-Term Impact, at 17 (Aug. 2011) ("[G]eneric drugs are commodity products marketed to wholesalers and drugstores primarily on the basis of price."); Congressional Budget Office, "How Increased Competition From Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry" (July 1998).

2005 and 2014.[9]

**B. Propranolol Has Been Sold in the United States for Decades**

53. Propranolol was developed in the 1960s.

54. Propranolol came to market under the brand name Inderal after FDA approval in 1967. For a time, this branded Propranolol was the best-selling drug in the world. In 2009, Akrimax acquired the rights to Inderal from Wyeth. Akrimax markets a branded formulation of Inderal to this day.

55. The Defendants are manufacturers of generic Propranolol in the United States. Generic forms of Propranolol have been available in the United States for decades.

**C. Consolidation in the Generic Drugs Industry**

56. Since 2005, consolidation has generally reduced the number of competitors in generic pharmaceutical markets. Consolidation reduces the number of potential competitors, rendering the market ripe for collusion

57. Generic pharmaceutical industry leader Defendant Teva, for example, acquired Ivax Corporation in 2006, Barr Laboratories in 2008, Ratiopharm—Germany's second largest generic drug producer— in 2010; and Allergan's generics business (including Actavis generics) in 2016. Other major transactions that occurred during the same time period include Watson Pharmaceuticals' acquisition of Andrx Corporation in 2006; Daiichi Sankyo's purchase of a

[9] Generic Pharmaceutical Association, Generic Drug Savings in the U.S., at 1 (2015), *available at* http://www.gphaonline.org/media/wysiwyg/PDF/GPhA_Savings_Report_2015.pdf.

majority stake in Ranbaxy in 2008; Defendant Endo's 2010 acquisition of Qualitest; Perrigo's acquisition of Paddock Laboratories, Inc. in 2011; and Sandoz's acquisition of Fougera in 2012.

58. As a result of this consolidation, Defendants dominate the market for the generic forms of Propranolol at issue here. Thus, the Defendants' concerted actions have had the ability to, and did, impact pricing and output in the United States.

**D. Propranolol Price Increases**

59. As part of their conspiracy, Defendants agreed to raise the prices of Propranolol sold in the United States.

60. A recent article in the American Journal of Health-System Pharmacy noted that there have been "massive price increases" on Propranolol.[10] A Los Angeles Times articles noted that Propranolol prices have been "skyrocket[ing]" leaving many older Americans unable to pay for this essential medicine.[11]

61. Over a six month period starting in late 2013, the price of Propranolol Capsules increased an average of 173%. Over a six month period starting in early 2015, the price of Propranolol Tablets increased an average of 736%.

62. There were no reasonable justifications for this abrupt shift in pricing by all Defendants on a drug product that had been marketed in the United States for more than fifty

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[10] Schumeck et al., *National trends in prescription drug expenditures and projections in 2016*, 73 Am. J. Health-Syst. Pharm. 357, 370 (July 16, 2016).

[11] Melody Petersen, *Drug costs skyrocket for many older Americans, despite Medicare coverage*, Los Angeles Times (Nov. 23, 2016), *available at* http://www.latimes.com/business/la-fi-medicare-drug-costs-20161123-story.html.

years (and had been available in generic form for decades).

63. Meanwhile, the Defendants have reported record revenues. For example, in a recent earnings call, Impax noted that Propranolol Tablets were a "large revenue" product. This was echoed in an Impax 8-K filed on November 9, 2016 that noted Propranolol was a "higher value product."

64. Trade association meetings, including those sponsored by GPhA, provided Propranolol manufacturers with the opportunity to meet and agree to fix Propranolol prices, and/or allocate markets and rig bids for Propranolol.

65. Many of the Defendants and/or their subsidiaries or affiliates are members of the GPhA. The GPhA describes itself as "the nation's leading trade association for manufacturers and distributors of generic prescription drugs, manufacturers of bulk active pharmaceutical chemicals, and suppliers of other goods and services to the generic industry."[12] The GPhA was formed in 2000, after the merger of three other generic drug trade associations—the Generic Pharmaceutical Industry Association, the National Association of Pharmaceutical Manufacturers, and the National Pharmaceutical Alliance.

66. Several of Defendants' high-ranking corporate officers also serve on GPhA's Board of Directors, including Mylan's Heather Bresch, Impax's Marcy Macdonald, Par's Tony Pera, and Teva's Debra Barrett. Ms. Bresch serves as the GPhA's current chair.

[12] Generic Pharmaceutical Association Website, About The Association, *available at* http://www.gphaonline.org/about/the-gpha-association.

67. Representatives from Defendants attended meetings held by GPhA. The following table lists some of the GPhA meetings attended by Defendants' employees:

| Meeting | Meeting Date and Location | Known Attendees |
|---|---|---|
| 2013 GPhA Fall Technical Conference | October 28 to 30, 2013 Bethesda, Maryland | Actavis, Teva, Impax, Mylan, Endo, Par, Heritage, Breckenridge, Upsher-Smith |
| 2014 GPhA Annual Meeting | February 19 to 21, 2014 Orlando, Florida | Actavis, Teva, Impax, Mylan, Endo, Par, Heritage, Breckenridge, Upsher-Smith |
| 2014 GPhA CMC Workshop | June 3-4, 2014 Bethesda, Maryland | Actavis, Teva, Impax, Mylan, Par, Heritage, Breckenridge |
| 2014 GPhA Fall Technical Conference | October 27 to 29, 2014 Bethesda, Maryland | Actavis, Teva, Impax, Mylan, Par, Heritage, Breckenridge, Upsher-Smith |
| 2015 GPhA Annual Meeting | February 9 to 11, 2015 Miami, Florida | Actavis, Teva, Impax, Mylan, Endo, Par, Heritage, Breckenridge, Upsher-Smith |
| 2015 GPhA CMC Workshop | June 9 to 10, 2015 Bethesda, Maryland | Actavis, Teva, Impax, Mylan, Par, Heritage, Breckenridge |

68. Since Defendants were selling a commodity product, absent an agreement to fix prices, if any Defendant increased its price it would expect to lose sales to other manufacturers. Thus, it would not be in any Defendant's unilateral self-interest to raise its price for generic Propranolol unless it had agreed with its competitors that they would also raise their prices.

69. As a result of Defendants' agreement, whenever certain Defendants raised their prices, others would soon follow. As reflected in price data developed by the National Association of State Medicaid Directors (National Average Drug Acquisition Cost, "NADAC"),

prices for Propranolol Capsules and Tablets have experienced dramatic increases as described in the charts below:

| Propranolol Capsule Dosage | Time Period | Average Price Increase |
|---|---|---|
| 60mg ER capsules | December 18, 2013 to July 23, 2014 | 164% |
| 80mg ER capsules | December 18, 2013 to September 17, 2014 | 174% |
| 120mg ER capsules | December 18, 2013 to July 23, 2014 | 181% |
| 160mg ER capsules | December 18, 2013 to October 22, 2014 | 174% |

| Propranolol Tablet Dosage | Time Period | Average Price Increase |
|---|---|---|
| 10mg tablet | February 18, 2015 to September 23, 2015 | 819% |
| 20mg tablet | February 18, 2015 to November 18, 2015 | 892% |
| 40mg tablet | February 18, 2015 to August 19, 2015 | 914% |
| 60mg tablet | February 18, 2015 to August 19, 2015 | 96% |
| 80mg tablet | February 18, 2015 to November 18, 2015 | 958% |

70. Defendants' coordinated pricing has deprived, and continues to deprive, Plaintiff and other direct purchasers of the benefits of free and open competition—namely lower prices for Propranolol. As a result, Plaintiff and other direct purchasers have paid and continue to pay non-competitive prices for Propranolol.

**E. Pretextual Justifications**

71. There are no market-based reasons for the pricing patterns in the generic Propranolol market. Defendants' price increases were not necessitated by increased manufacturing costs because Defendants realized record profits from generic Propranolol sales during the relevant period.

72. The price increases were likewise not incurred to defray the cost to invent and develop the original Propranolol to bring it to market, which Defendants—manufacturers of generic, not the innovator version of Propranolol—did not incur in connection with the at-issue products.

73. At the times Propranolol prices rose, there were no known raw material shortages that would have constrained Defendants' ability to supply the market. Federal law requires drug manufacturers to report potential drug shortages to the FDA. No supply disruption was reported by Defendants with respect to Propranolol during the Class Period.

74. Thus, any justifications for the price increases would be pretextual.

75. Accordingly, through their anticompetitive agreement to fix, increase, and maintain the price of generic Propranolol, Defendants were able to substantially increase their revenues without having made investments in research, development, or other costs associated with bringing brand name Propranolol to market.

**F. Government Investigations**

76. As noted above, Defendants' conduct in regards to generic drugs is under

investigation by Congress, the DOJ, state attorneys general, and others.

77. The fact that several of these companies and/or their employees received subpoenas from a federal grand jury is significant, as is reflected in Chapter 3 of the 2014 edition of the DOJ's Antitrust Division Manual.[13] Section F.1 of that chapter notes that "staff should consider carefully the likelihood that, if a grand jury investigation developed evidence confirming the alleged anticompetitive conduct, the Division would proceed with a criminal prosecution." *Id.* at III-82. The staff request needs to be approved by the relevant field chief and is then sent to the Antitrust Criminal Enforcement Division. *Id.* "The DAAG [Deputy Assistant Attorney General] for Operations, the Criminal DAAG, and the Director of Criminal Enforcement will make a recommendation to the Assistant Attorney General. If approved by the Assistant Attorney General, letters of authority are issued for all attorneys who will participate in the grand jury investigation." *Id.* at III-83. "The investigation should be conducted by a grand jury in a judicial district where venue lies for the offense, such as a district from or to which price-fixed sales were made or where conspiratorial communications occurred." *Id.* Thus, the fact that one or more of the Defendants and certain of their employees received federal grand jury subpoenas is an indication that antitrust offenses have occurred.

78. That a target has applied for leniency is also significant. As the DOJ notes on its web site (http://www.justice.gov/atr/frequently-asked-questions-regarding-antitrust-divisions-

[13] *Available at* http://www.justice.gov/atr/public/divisionmanual/chapter3.pdf.

leniency-program):

> **5. Does a leniency applicant have to admit to a criminal violation of the antitrust laws before receiving a conditional leniency letter?**
>
> Yes. The Division's leniency policies were established for corporations and individuals "reporting their illegal antitrust activity," and the policies protect leniency recipients from criminal conviction. Thus, the applicant must admit its participation in a criminal antitrust violation involving price fixing, bid rigging, capacity restriction, or allocation of markets, customers, or sales or production volumes before it will receive a conditional leniency letter. Applicants that have not engaged in criminal violations of the antitrust laws have no need to receive leniency protection from a criminal violation and will receive no benefit from the leniency program.

The DOJ further provides that the leniency applicant must also satisfy the following condition, among others, to avail itself of the government's leniency: "[t]he confession of wrongdoing is truly a corporate act, as opposed to isolated confessions of individual executives or officials." *Id*.

79. The DOJ is poised to issue criminal indictments against various companies and individuals growing out this investigation and, as indicated above, issued its first two on December 12, 2016. On December 14, 2016, Bloomberg reported that "[t]he Justice Department accused two executives of colluding with other generic pharmaceutical companies to fix prices, the first criminal charges stemming from a sweeping two-year investigation. Jeffrey Glazer, a former chief executive officer of Heritage Pharmaceuticals Inc., and Jason Malek, an ex-president, were charged in Philadelphia on Wednesday, according to court filings."[14] As noted

[14] Tom Schoenberg, *U.S. Generic Drug Probe Seen Expanding After Guilty Pleas*, Bloomberg (Dec. 14, 2016), *available at* https://www.bloomberg.com/news/articles/2016-12-14/u-s-files-first-charges-in-generic-drug-price-fixing-probe.

above, Mr. Glazer and Mr. Malek reportedly discussed selling Propranolol at a "high price" in early 2015.

80. Twenty states attorneys general led by the State of Connecticut also filed their first action (relating to the generic drugs Glyburide and Doxycycline) based on their investigation into generic drug pricing on December 15, 2016.[15] They have indicated that more actions are likely to follow, specifically alleging that they "have uncovered a wide-ranging series of conspiracies implicating numerous different drugs and competitors, which will be acted upon at the appropriate time..."[16] The states attorneys general describe these conspiracies as "schemes to fix and maintain prices, allocate markets and otherwise thwart competition" and explain that they are carried out by generic companies through their senior executives who "exploit their interactions at various and frequent industry trade shows, customer conferences and other similar events, to develop relationships and sow the seeds for their illegal agreements. The anticompetitive agreements are further refined and coordinated at regular 'industry dinners', 'girls nights out', lunches, parties, and numerous and frequent telephone calls, emails and text messages." *Id.* at ¶¶ 7-8. Connecticut's attorney general George C. Jepsen commented on the suit that:

[15] Complaint, *State of Connecticut v. Aurobindo Pharma USA*, 16-cv-2056-VLB (D. Conn. Dec. 15, 2016), ECF No. 1.

[16] *Id.* at ¶ 9.

> We believe this is just the tip of the iceberg. I stress that our investigation is continuing, and it goes way beyond the two drugs in this lawsuit, and it involves many more companies than are in this lawsuit.[17]

Mr. Jepsen further commented that in the generic drug industry in the United States there is "a culture of cronyism where, whether it's over a game of golf or a dinner or drinks, there's just systematic cooperation."

81. The United States Congress has been probing generic drug pricing for at least the last few years. In October 2014, U.S. Senator Bernie Sanders and U.S. Congressman Elijah Cummings sent letters to several generic drug manufacturers concerning price increases. In November 2014, a Senate committee held a hearing entitled "Why Are Some Generic Drugs Skyrocketing In Price?"[18] Most recently, in December 2016, the United States Senate Special Committee on Aging issued a lengthy report on drug pricing noting that its investigation "uncovered disturbing practices in pharmaceutical drug pricing."[19]

**G. The Generic Drug Market is Extraordinarily Susceptible to Collusion**

82. In addition to the pricing allegations set forth above, several market and other relevant factors give rise to a reasonable inference that Defendants acted unlawfully and in

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[17] Katie Thomas, *20 States Accuse Generic Drug Companies of Price Fixing*, The New York Times (Dec. 15, 2016), *available at* http://www.nytimes.com/2016/12/15/business/generic-drug-price-lawsuit-teva-mylan.html.

[18] *See*, *e.g.*, U.S. Congress Press Release, *Congressional Panel to Probe Generic Drug Price Hikes* (Nov. 11, 2014), *available at* http://democrats.oversight.house.gov/news/press-releases/congressional-panel-to-probe-generic-drug-price-hikes.

[19] United States Senate Special Committee on Aging, Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System (Dec. 2016).

concert to raise and fix Propranolol prices far above competitive levels. The United States market for generic Propranolol has been characterized by numerous factors that facilitated Defendants' conspiracy, including: (1) high degree of industry concentration; (2) barriers to entry; (3) demand inelasticity; (4) lack of substitution; (5) high degree of interchangeability; (6) absence of competitive sellers; and (7) opportunities to conspire.

i. High Degree of Industry Concentration: As discussed above, a small number of competitors control a significant market share for generic Propranolol.

ii. Barriers to Entry: Costs of manufacture, intellectual property, and expenses related to regulatory oversight are barriers to entry in the generic drug market. Barriers to entry increase the market's susceptibility to a coordinated effort to maintain supracompetitive prices.

iii. Demand Inelasticity: generic Propranolol is a necessary treatment for millions of patients.

iv. Lack of Substitutes: Many patients are unable to substitute other medications for generic Propranolol.

v. High Degree of Interchangeability: Defendants' generic Propranolol products are interchangeable within each dosage form, as they contain the same chemical compounds made from the same raw materials. Thus, generic Propranolol products are standardized across suppliers and are highly interchangeable from one Defendant to the next.

vi. Absence of Competitive Sellers: Defendants have maintained supracompetitive pricing for generic Propranolol throughout the Class Period. Thus, Defendants have oligopolistic market power in the generic Propranolol market, which enables Defendants to increase prices without losing market share.

vii. Opportunities for Contact and Communication Among Competitors: As discussed above, certain Defendants are members of trade association GPhA and/or common attendees to GPhA meetings which provides and

promotes opportunities to communicate.

## VI. CLASS ACTION ALLEGATIONS

83. Pursuant to Federal Rules of Civil Procedure 23(a) and (b)(3), Plaintiff brings this action on behalf of a Class defined as follows:

> All persons or entities that directly purchased: (a) Propranolol Capsules from Defendants in the United States and its territories and possessions at any time during the period December 1, 2013 until the anticompetitive effects of Defendants' conduct cease; and/or (b) Propranolol Tablets from Defendants in the United States and its territories and possessions at any time during the period February 1, 2015 until the anticompetitive effects of Defendants' conduct cease.
>
> Excluded from the Direct Purchaser Class are Defendants and their officers, directors, management, employees, subsidiaries, or affiliates, and all federal governmental entities.

84. Members of the Class are so numerous that joinder of all members is impracticable. Plaintiff believes the Class members are numerous and widely dispersed throughout the United States. Further, the Class members are readily identifiable from information and records maintained by Defendants.

85. Plaintiff's claims are typical of the claims of the members of the Class. Plaintiff's interests are not antagonistic to the claims of the other Class Members, and there are no material conflicts with any other member of the Class that would make class certification inappropriate. Plaintiff and all members of the Class were damaged by the same wrongful conduct of Defendants.

86. Plaintiff will fairly and adequately protect and represent the interests of the

Class. The interests of the Plaintiff are coincident with, and not antagonistic to, those of the Class.

87. Plaintiff is represented by counsel who are experienced and competent in the prosecution of class action litigation, and who have particular experience with class action litigation involving alleged violations of antitrust law in the pharmaceutical industry.

88. Questions of law and fact common to the members of the Class predominate over questions that may affect only individual Class Members because Defendants have acted on grounds generally applicable to the entire Class, thereby determining damages with respect to the Class as a whole is appropriate. Such generally applicable conduct is inherent in Defendants' wrongful conduct.

89. The common legal and factual questions, which do not vary from Class Member to Class Member and which may be determined without reference to individual circumstances of any Class Member, include, but are not limited to, the following:

(a) Whether Defendants and their co-conspirators engaged in a contract, combination, or conspiracy to eliminate competition and thereby artificially increase the prices of generic Propranolol in the United States;

(b) The duration and extent of the alleged contract, combination, or conspiracy;

(c) Whether Defendants and their co-conspirators were participants in the contract, combination, or conspiracy alleged herein;

(d) The effect of the contract, combination, or conspiracy on the prices of generic

Propranolol in the United States during the Class Period;

(e) Whether Defendants' conduct caused supracompetitive prices for generic Propranolol;

(f) Whether, and to what extent, the conduct of Defendants and their co-conspirators caused injury to Plaintiff and other members of the Class; and

(g) Whether the alleged contract, combination, or conspiracy violated Section 1 of the Sherman Act, 15 U.S.C. § 1.

90. Class action treatment is a superior method for the fair and efficient adjudication of the controversy. Such treatment will permit a large number of similarly situated persons or entities to prosecute their common claims in a single forum simultaneously, efficiently, and without the unnecessary duplication of evidence, effort, or expense that numerous individual actions would engender. The benefits of proceeding through the class mechanism, including providing injured persons or entities a method for obtaining redress on claims that could not practicably be pursued individually, substantially outweighs potential difficulties in management of this class action.

91. Plaintiff knows of no special difficulty to be encountered in the maintenance of this action that would preclude its maintenance as a class action.

## VII. ANTITRUST INJURY

92. During the Class Period, Plaintiff and Class Members directly purchased generic Propranolol from Defendants. As a result of the Defendants' anticompetitive conduct, Plaintiff and Class Members paid more for generic Propranolol than they would have and thus suffered

substantial damages. This is a cognizable antitrust injury and constitutes harm to competition under the federal antitrust laws.

93. Because Defendants' unlawful conduct has successfully eliminated competition in the market, and Plaintiff and Class Members have sustained, and continue to sustain, significant losses in the form of artificially inflated prices paid to Defendants. The full amount of such damages will be calculated after discovery and upon proof at trial.

94. Defendants' misconduct reduced competition in the generic Propranolol market, reduced choice for purchasers, and caused injury to purchasers.

95. Defendants' anticompetitive conduct is ongoing, and as a result Plaintiff and the Class continue to pay supracompetitive prices for generic Propranolol.

## VIII. CLAIM FOR RELIEF
## VIOLATION OF SECTION 1 OF THE SHERMAN ACT, 15 U.S.C. § 1

96. Plaintiff incorporates and re-alleges, as though fully set forth herein, each of the paragraphs set forth above.

97. Defendants are per se liable under Section 1 of the Sherman Act, 15 U.S.C. § 1, for the injuries and damages caused by their contract, combination, and conspiracy in restraint of trade as alleged herein.

98. There is no legitimate, non-pretextual, procompetitive business justification for Defendants' conspiracy that outweighs its harmful effect. Even if there were some conceivable justification, the conspiracy is broader than necessary to achieve such a purpose.

99. As set forth above, in violation of Section 1 of the Sherman Antitrust Act,

Defendants entered into agreements with one another on the pricing and allocation of the market for Propranolol in the United States. This conspiracy was per se unlawful price-fixing, or alternatively, was an unlawful restraint of trade under the rule of reason.

100. Each Defendant has committed at least one overt act to further the conspiracy alleged in this Complaint.

101. The conspiracy had its intended effect, as Defendants benefited from their collusion and the elimination of competition, both of which artificially inflated the prices of generic Propranolol, as described herein.

102. As a result of Defendants' unlawful conduct, Plaintiff and Class Members have been injured in their business and property in that they have paid more for generic Propranolol than they otherwise would have paid in the absence of Defendants' unlawful conduct. The full amount of such damages is presently unknown but will be determined after discovery and upon proof at trial.

## IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff and Class Members pray for relief as set forth below:

A. Certification of the action as a class action pursuant to Federal Rule of Civil Procedure 23, and appointment of Plaintiff as Class Representative and its counsel of record as Class Counsel;

B. That acts alleged herein be adjudged and decreed to be unlawful restraints of trade in violation of the Sherman Act, 15 U.S.C. § 1;

C. A judgement against Defendants, jointly and severally, for the damages sustained by Plaintiff and the Class defined herein, and for any additional damages, penalties, and other monetary relief provided by applicable law, including treble damages;

D. By awarding Plaintiff and Class Members pre-judgment and post-judgment interest as provided by law, and that such interest be awarded at the highest legal rate from and after the date of service of the Complaint in this action;

E. The costs of this suit, including reasonable attorney fees; and

F. Such other and further relief as the Court deems just and proper.

## X. DEMAND FOR JURY TRIAL

Plaintiff, on behalf of itself and others similarly situated, hereby requests a jury trial, pursuant to Federal Rule of Civil Procedure 38, on any and all claims so triable.

Dated: December 28, 2016

Respectfully submitted,

NASTLAW LLC

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